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510(k) Summary

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Device Name: NICaS 2001 Noninvasive Cardio-Respiratory System

Common Name: Noninvasive Cardio-Respiratory Monitor

Classification Name: Impedance plethysmography (21 CFR 870.2770)

Predicate Device: BoMed's NCCOM3-R7 Monitor

Device Description: The NICaS 2001 is a noninvasive cardio-respiratory monitor which utilizes bioimpedance measurements from the blood circulatory system to calculate hemodynamic parameters (including stroke volume, stroke index, heart rate, cardiac output, cardiac index and total peripheral resistance) and ventilatory parameters (including respiratory rate). The NICaS 2001 uses 4 electrodes that pick up the signals which are amplified inside the patient module. After signal amplification and filtration, the analysis is done by a powerful microprocessor. The microprocessor-driven software includes unique algorithms that reject artifacts and perform all required calculations for stroke volume (SV) and other derived parameters. The results are displayed on a PC screen. The software allows data storage, recall/review and printout. The electrodes are nondisposable (standard electrode by Nicolet) "strap" style attached to cable leads. These electrodes consist of two 55 cm electrode strips for the leg and two 25 cm electrode strips for the arm. The electrodes are attached to the two identified input connectors of the patient module. The patient module also connects with the computer.

Intended Use:

The NICaS 2001 is intended for use in monitoring hemodynamic parameters (including stroke volume, stroke index, heart rate, cardiac index, cardiac output, and total peripheral resistance) and ventilatory parameters (respiratory rate) in males and females needing cardiac output assessment, including patients with cardiovascular disorders, patients undergoing cardiac catheterization, cardiac surgery patients and patients in intensive and cardiac care units and rehabilitation.

Precaution:

The effective use of the NICaS 2001 has not been established in the following clinical conditions:

- * Severe valvular disease
- * Severe septic shock
- * Severe aortic aneurysms
- * Occlusion of the abdominal aorta or aortic bifurcation
- * Peripheral arterial disease
- * Coarctation of the aorta
- * Chaotic breathing patterns
- * Intra cardiac shunts
- * Severe arrhythmias
- * Dialysis

Comparison of Technological Characteristics:

The NICaS 2001 and the BoMed NCCOM3-R7 derive parameters such as stroke volume, cardiac output and other related cardiac parameters by analyzing the impedance changes in the body as influenced by the pumping action of the heart. A modified Kubicek algorithm is used in both devices.

Differences between the NICaS 2001 and the BoMed NCCOM3-R7:

The NICaS 2001 measures total body impedance, which includes both the peripheral and the thorax areas, while BoMed measures only thoracic impedance. This methodology is based on modification of the Kubicek algorithm, the inclusion of patient data (i.e., weight and height), so that a final analysis can provide parameters relative to total body measurement and not only thoracic parameters.

The NICaS 2001 technology allows the display of the respiratory wave as an optional reference for the clinician.

The following parameters are included in the BoMed NCCOM3-R7 but are not displayed on the NICaS 2001: dZ/dt , pre ejection time, ejection time, peak flow, ejection fraction and end diastolic volume. The thoracic fluid index (TFI) is not available by the NICaS 2001 because the device can not distinguish between the thorax and the peripheral; they are measured together in the NICaS 2001. The TFI is not needed for any other calculation.

Safety and Effectiveness Information:

The NICaS 2001 was designed to meet the IEC 601-1, IEC 601-1-1 and UL 544 medical safety standards. It was tested and approved by TUV.

Data collected from a study conducted by Dr. H. Miller at the Ichilov Hospital, Israel, correlated cardiac output by the NICaS 2001 with the standard invasive technique of thermodilution. Data collected from a study conducted by Dr. Michael Luchansky at the Tel Aviv Medical Center correlated the respiratory rate measured with the Horizon 2000 Physiological Monitor with the NICaS 2001.